OMB INFORMATION COLLECTION
SUPPORTING STATEMENT
0910-0116

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of OMB Control No. 0910-0116 and OMB approval of the information collection requirements in 21 CFR Parts 606 and 640 (Tab A), Current Good Manufacturing Practices (CGMPs) and Related Regulations for Blood and Blood Components:

21 CFR 606.100(b)	Recordkeeping	Requires that written standard operating procedures (SOPs) be maintained for the collection, processing, compatibility testing, storage and distribution of blood and blood components used for transfusion and manufacturing purposes.
21 CFR 606.100(c)	Recordkeeping	Requires the review of all records pertinent to a lot or unit of blood prior to release of the lot or unit. Conclusions and followup of any unexplained discrepancy or failure of a lot or unit of final product to meet any of its specifications shall be recorded.
21 CFR 606.110(a)	Recordkeeping	Requires a physician to certify in writing that the donor's health permits plateletpheresis or leukapheresis if a variance from additional regulatory standards for a specific product is used when obtaining the product from a specific donor for a specific recipient.
21 CFR 606.110(b)	Reporting	Requires establishments to request prior CBER approval for plasmapheresis of donors who do not meet donor requirements.
21 CFR 606.121	Disclosure	Requires container label for blood and blood components by all blood establishments.
21 CFR 606.122	Disclosure	Requires an instruction circular, containing adequate directions for use, be available for distribution if the product is intended for transfusion.
21 CFR 606.151(e)	Recordkeeping	Requires that records of expedited transfusions in life-threatening emergencies be maintained, to allow clear tracing of all steps in the collection, processing, compatibility testing, storage and distribution, quality control, and transfusion reaction reports and complaints for each unit of blood and blood components.
21 CFR 606.160	Recordkeeping	Requires that legible and indelible contemporaneous records of each significant step be made and maintained for no less than 5 years.

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21 CFR 606.165	Recordkeeping	Requires that distribution and receipt records be maintained to facilitate recalls, if necessary.
21 CFR 606.170(a)	Recordkeeping	Requires records to be maintained of any reports of complaints of adverse reactions as a result of blood collection or transfusion, and a written report, including conclusions and followup, must be prepared and maintained.
21 CFR 606.170(b)	Reporting	Requires that fatal complications of blood collections and transfusions be reported to FDA as soon as possible and that a written report shall be submitted within 7 days.

In addition to the CGMPs in part 606, there are regulations in part 640 that require additional standards for blood and blood components: §§640.3(a), 640.2(f), 640.4(a), 640.25(b)(4) and (c)(1), 640.27(b), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1) and (e)(3), 640.65(b)(2), 640.66, 640.71(b)(1), 640.72, 640.73, and 640.76(a) and (b). The information collection requirements and estimated burdens for these regulations are included in the part 606 burden estimates, as described in section 12.

Under the statutory requirements contained in the Public Health Service Act (42 U.S.C. 262, Tab B), no blood, blood component, or derivative may move in interstate commerce unless: (1) It is propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license; (2) the product complies with regulatory standards designed to ensure safety, purity, and potency; and (3) it bears a label plainly marked with the product's proper name, its manufacturer, and expiration date. The CGMP and related regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components.

2. Purpose and Use of the Information

The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections. The recordkeeping requirements serve preventative and remedial purposes. These objectives necessitate recordkeeping at each step in a continuous process which originates in donor enlistment and concludes in testing of the unit of blood for suitability for use and compatibility testing. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of any deviations that occur and that may require immediate corrective action.

3. Use of Information Technology and Burden Reduction

Establishments may use computer tapes, discs, microfiche or microfilm in lieu of hard copy records for the purpose of maintaining records. Computers may be used for filing reports to FDA. FDA is not aware of any other improved technology to reduce the burden except that unautomated blood establishments could reduce the time required to maintain records with respect to input and retrieval by becoming computerized.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requests this information. There is no similar kind of information available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its duty requires the equal application of the regulations to all enterprises. The likelihood of contracting a contagious disease from a unit of blood collected from a small blood establishment is just as great as one collected from a large blood establishment. Consequently, the CGMPs must apply equally to both small and large manufacturers to adequately protect the nation's blood donors and recipients. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Training, and Manufacturer's Assistance provides assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Less frequent collection of information or other methods of reducing the frequency of collection would negate the purpose of on-site inspection of products, procedures, and records. It would not provide the necessary information needed by FDA to ensure safety, purity, and potency of blood and blood components and to protect the public health of the nation.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There is no special circumstances for the collection of the information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of July 6, 2000 (65 FR 41674, Tab C). *No comments were received from the public*.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be consistent with the Freedom of Information (FOI) Act and the agency's regulations under 21 CFR Part 20. After a FDA investigator completes a routine inspection of a blood or blood component manufacturing establishment, the completed report with the results of the inspection become public information, available under the FOI Act. However, certain information, such as donor and patient names, for example, is deleted from any information released by FDA under the FOI Act and FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature must be asked by establishments as part of the donor screening process for blood collection. These questions are used to evaluate the suitability of a donor. Donors not meeting certain criteria are deferred from donating. This information is necessary to help prevent the transmission of communicable diseases and protect public health. These records are maintained by the establishment and may be reviewed by FDA during an inspection.

12. Estimates of Hour Burden Including Annualized Hourly Costs

The estimated annual burden for this information collection is 332,403 hours.

Estimated Annual Reporting Burden					
21 CFR Section[1]	No. of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
606.170(b)	75	1	75	20	1,500

[1]The reporting requirement in §640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for §606.170(b).

The total annual responses in the reporting chart for fatality reporting are based on an annual average of fatality reports submitted to FDA.

Estimated Annual Recordkeeping Burden					
21 CFR Section[1]	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)	322[2]	1	322	24	7,728
606.100(c)	152[3]	26	4,000	1	4,000
606.110(a)	68[4]	5	340	0.5	170
606.151(e)	322[2]	12	3,864	0.083	321
606.160	322[2]	1,677	540,000	0.5	270,000
606.165	152[3]	3,553	540,000	0.083	44,820
606.170(a)	322[2]	12	3,864	1	3,864
TOTAL					330,903

[1]The recordkeeping requirements in §§ 640.3(a)(1), 640.4(a)(1), and 640.66, which address the maintenance of SOPs, are included in the estimate for §606.100(b); the recordkeeping requirements in §640.27(b), which address the maintenance of donor health records for plateletpheresis, are included in the estimate for §606.110(a); and the recordkeeping requirements in §§640.3(a)(2), 640.2(f), 640.3(f), 640.4(a)(2), 640.25(b)(4) and (c)(1), 640.31(b), 640.33(b), 640.51(b), 640.53(c), 640.56(b) and (d), 640.61, 640.63(b)(3), (e)(1) and (e)(3), 640.65(b)(2), 640.71(b)(1), 640.72, and 640.76(a) and (b), which address the maintenance of various records, are included in the estimate for §606.160.
[2]5% of HCFA and FDA registered blood establishments (0.05 X (3,400+3,032)).
[3]5% of FDA registered establishments (3,032)
[4]5% of pheresis establishments (1,349)

Based on FDA's registration system, there are an estimated 3,032 registered blood establishments inspected by FDA of which 1,349 perform pheresis. Based on information provided by HCFA, there are an estimated 3,400 transfusion services inspected by HCFA. An estimated 27,000,000 units of Whole Blood and blood components are collected annually. The recordkeeping chart reflects the

estimate that 95 percent of the recordkeepers which collect 98 percent of the blood supply had developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOPs developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

The annual frequency of recordkeeping and total annual records, and the estimated reporting and recordkeeping burden hours are based on information provided by industry, and FDA's experience. Under section 606.110(b), licensed establishments submit supplements to their biologics license applications to request prior CBER approval of plasmapheresis donors who do not meet donor requirements. The information collection requirements for section 606.110(b) are reported under OMB control number 0910-0315.

The development of labels is a one-time burden. The container labels have been standardized and are sold commercially. The label is only customized for the firm's name and address. In addition, the instruction circular is printed by major blood banking associations, ARC, AABB and ABC, and are sold at minimal cost to the firms. The circulars are updated annually usually due to new industry information. Therefore, no burden is imposed by FDA regarding the labeling and disclosure regulations (§§606.121 and 606.122) and guideline.

Cost to Respondents

The estimated annual cost to respondents is $8,655,978.

Activity	No. of Hours	Cost per Hour	Total Cost
Recordkeeping	330,903	$26	$8,603,478
Reporting	1,500	$35	$52,500
TOTAL			$8,655,978

The cost estimate is based on a pay rate of $26/hour for a medical technologist, who has the training and skills to handle various recordkeeping requirements. The cost estimate is also based on a supervisor, at a pay rate of $35/hour who would be responsible for investigating, writing, and reporting a fatality. These salary estimates include benefits but no overhead costs.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no capital and start-up, or operation, maintenance and purchase costs associated with the collection of information requirements.

14. Annualized Costs to the Federal Government

The estimated annualized cost to the Federal Government is $4,038,240. This estimate is based on a FDA investigator at an average grade scale of GS-12/5 ($33/hour) who performs on-site inspections. This cost includes inspection of a facility, review of facility records, and report preparation. The total estimated cost is also based on a GS-13/5 ($40/hour) Consumer Safety Officer who compiles, reviews, and analyzes fatality reports. These salary estimates include benefits but no overhead costs.

Activity	Number of Respondents	Hours per Response	Cost per Hour	Total Cost
Inspection	3,032	40	$33	$4,002,240
Fatality Report Review	75	12	$40	$36,000
TOTAL				$4,038,240

15. Explanation of Program Changes or Adjustments

The estimated total annual burden for this information collection requirement was 283,400 hours in 1997. The current increase to 332,403 burden hours is mostly attributed to the revised estimate number of respondents and the increase in the number of units of Whole Blood and blood components collected annually.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.